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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,570	09/29/2004	Jamea R. Trinkle	CGL01/0044US1	8359
38550 7590 10/01/2007 CARGILL, INCORPORATED LAW/24 15407 MCGINTY ROAD WEST WAYZATA, MN 55391			EXAMINER BLAND, LAYLA D	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 10/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,570	Applicant(s) TRINKLE ET AL.	
	Examiner Layla Bland	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/6/2007, 8/16/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is a response to applicant's amendment submitted August 16, 2007, wherein claims 1 and 7 are amended and new claims 11-18 are added. This application is a national stage entry of PCT/US03/10560, filed April 2, 2003 and claims priority to U.S. Provisional Application No. 60/369594, filed April 2, 2002. Claims 1-7 and 11-18 are currently pending in this application and are examined on the merits herein.

Applicant's amendment submitted August 16, 2007 is found to be persuasive to remove the objection to the specification, as the specification no longer contains graphical illustrations.

Applicant's amendment submitted August 16, 2007 is found to be persuasive to remove the rejections of claims 1-5 and 7 under 35 USC 102 and claim 6 under 35 USC 103, as the claims have been amended to state that the reaction occurs for at least 4 hours.

The following are new rejections necessitated by applicant's amendment submitted August 16, 2007. The addition of "for at least 4 hours" in claim 1 and "greater than 15 hours" in claim 7 overcomes the previous rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11 and 12 recite the limitation, "wherein the caustic is 5% to 40% (15% to 30%) by weight." It is unclear whether this limitation refers to the weight of the caustic itself in relation to the total weight of the mixture, or the percent solution of caustic, or the weight of a caustic solution in relation to the total weight of the mixture.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (Journal of Food Biochemistry 23 (1999) 187-196, of record) in view of Konda et al. (Biol. Pharm. Bull. 23(12) 1458-1464 (2000)).

Hu et al. teach a two-step extraction method for fungal chitosan which provides chitosan essentially free of impurities [see abstract]. Fungal mycelia were autoclaved (about 15 psig) in a 1M-50% caustic soda solutions at 121° C for 15-60 minutes [Table

1]. The alkali-insoluble materials obtained were then further autoclaved in aqueous acetic acid solution [abstract]. After extraction, the chitosan was washed and centrifuged, freeze-dried and weighed [page 190, Chitosan Extraction]. Concentrated alkali (50%) produced the highest yield of chitosan [page 191, Table 1]. The longest extraction (60 min) produced chitosan with the lowest molecular weight [page 192, lines 16-18].

Hu et al. do not teach reaction times longer than 1 hour, pressure higher than 15 psig, or temperature higher than 121°C.

Butelman, et al. teach the extraction of chitosan from arthropod waste material with saturated steam under pressure in the presence of an alkaline agent [abstract]. A mixture of shells derived from crustaceans and caustic soda solution is treated with saturated steam at a temperature of between 150 and 300° C and a pressure between 15 and 30 bar (about 217-435 psig) for 2-15 minutes [column 2, lines 31-42]. The method produces complete disgregation of the starting material [column 2, lines 45-50]. The chitosan product has molecular weight of 20,000-100,000 and deacetylation greater than 95% [column 3, lines 12-18].

Konda et al. teach that administration of low molecular weight chitosan prevents the progression of non-insulin-dependent diabetes in mice [page 1464, last paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce chitosan by reacting fungal biomass with sodium hydroxide, at elevated temperature and pressure, for long periods of time. The use of elevated temperatures and pressures and varied concentrations of caustic is already

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known in the art, as taught by Hu et al. and Butelman et al. The skilled artisan would have been motivated to employ long reaction times in order to produce lower molecular weight chitosan, as taught by Hu et al., because low molecular weight chitosan has desirable properties, as taught by Konda et al. One of ordinary skill in the art would understand that temperature, pressure, reaction time, and concentration are all parameters that are easily manipulated to drive reactions forward. Thus, the skilled artisan, using the above references for guidance, could optimize these parameters to achieve chitosan having the desired molecular weight and degree of deacetylation.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

It is noted that limitations such as "for at least 4 hours," "pressure greater than 0 psig," and "temperature greater than 125°C," have no upper limit and therefore are unclear.

Response to Arguments

Applicant's arguments with respect to the rejections of claims 1-7 under 35 USC 102 and 35 USC 103 have been considered but are not persuasive.

Applicant argues that there is no teaching or suggestion that higher temperatures can improve the quality of chitosan obtained. First, It is unclear what is considered high quality chitosan; there is no mention of quality or chitosan properties in the claims. Second, the skilled artisan would understand that increasing temperature is one way of increasing the rate of a reaction; thus, for example, temperature manipulation may be used to obtain chitosan more quickly and/or in higher yield.

Applicant argues that there is no teaching or suggestion in the cited references that reactions performed for at least 4 hours will produce chitosan of higher quality. Applicant asserts that the cited references teach away from using longer incubation times. Again, it is unclear what is considered high quality chitosan. As discussed above, low molecular weight chitosan has desirable properties and long incubation times at increased pressure can produce chitosan of low molecular weight, as taught by Hu et al.

Moreover, Applicant asserts that the claimed method produces chitosan of unexpected and superior quality, based on the data given in Tables 1-5. Again, it is unclear what is considered high quality chitosan and no mention of such is recited in the claims.

Applicant argues that the claimed method produces chitosan of 43-98.4% or 53-94% purity. These ranges are very broad and cannot be considered unexpected. Also note that the chitosan produced by the method of Hu et al. is "essentially free of impurities." [see abstract]

Applicant argues that the deacetylation of chitosan produced by the claimed method is 79-89% or 82-93%. These ranges fall between the values reported by Hu et al. and Butelman et al. and thus are not unexpected.

Applicant argues that the claimed method produces chitosan having molecular weight over 100,000. The data in Tables 1 and 2 seems to imply that the molecular weight of chitosan goes up for the first 12-15 hours of incubation and then begins to go down. Because molecular weight goes down as the product is degraded, a trend in one direction would be more likely than increase followed by decrease. Thus, the data given in Tables 1 and 2 is not seen as sufficient to support applicant's arguments regarding molecular weight.

Although applicant argues that the values obtained were significantly better than those obtained in the prior art, no side-by-side comparison has been made.

Therefore, the evidence presented in the specification herein is not seen to be clear and convincing to support the nonobviousness of the instant claimed invention over the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
September 18, 2007

Shaojia Anna Jiang


Supervisory Patent Examiner
Art Unit 1623
September 18, 2007